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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/874,580 | 06/05/2001 | Richard A. Brauckman | TGXX-1003US | 6921 |

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EXAMINER

WEBB, SARAH K

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3731

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/874,580

Applicant(s)

BRAUCKMAN ET AL.

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 28-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26, 28-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claims 1-35 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,261,320 to Tam et al.

The stent of Tam includes all the limitations of the claimed invention. Figure 20C shows the many layers that form the rolled foil stent structure. *"The term 'coating' is intended to cover generically any form of material which is ...adjacent the surface of the stent, such as a jacket or thin film..."* (column 20, paragraph 3). The innermost layer (310) is analogous to the flexible stent in the claims, while an outer layer (312) is analogous to the foil sheet of the claims. The radioactive sheet (312) can have palladium 103 isotopes (column 22, line 26) and is located on the outer diameter of the stent (310). The radioactive film can also include a coating (311 or 314) on one side, which can be titanium (col 22, line 61- col 23, line 3). The stent layer (310) supports the coating layers (311 and 312) and forces the coating to expand as it expands.

Tam explains that the coatings can contain drugs, such as heparin, and can be bioabsorbable (column 20, paragraph 4). Figure 14 shows tabs (190) protruding from the

outer layer of the device that provide mechanical attachment for securing the stent in the treatment site. Tam further explains that cyanoacrylate, or adhesive, can be applied as a coating (column 30). The sheets further include perforations (Figures 2, 4, 5), which form a *mesh* or screen structure. Tam explains that no unwanted isotopes are formed in the radioactive coating (column 26, line 23), so the palladium-103 would be carrier free.

Figures 1,7,9,10, and 12 show the stent, as described above, delivered by an insertion device, or catheter (120).

Response to Arguments

2. Applicant's arguments filed 1/13/03 with respect to the rejection of claims 1-35 have been fully considered but are not persuasive. In response to applicant's argument that the Tam references fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "two-element structure") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Examiner considers the Tam reference to include all the limitation of the *claimed* structure. As explained above, an inner layer forms the stent, which is one element, while an outer layer forms the sheet, which is a second element. The requirement of the *claimed* foil sheet is only that it be "located adjacent the stent". The claims do not require for the stent and foil sheet to be unattached or separate, only "adjacent" to one another. The term "adjacent" is very broad, so the radioactive sheet attached to the outer surface of the stent of Tam was interpreted to meet this limitation. Tam explains that the coating, or outer layer, includes structures such as

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foil sheets: “*The term ‘coating’ is intended to cover generically any form of material which is ...adjacent the surface of the stent, such as a jacket or thin film...*” (column 20, paragraph 3).

The radioactive sheet is on the outer surface of the device, so the radioactive material would inherently be in direct contact with the wall of the blood vessel.

Applicant further argues that the method of insertion in the Tam reference does not meet the steps of claim 26. Claim 26 does not require for the sheet to be separate from the stent or catheter, only “associated” with the insertion device. “Associated” is a broad term that is interpreted to include “adjacent”, where the sheet is “adjacent” to the stent (see Tam quote above). The sheet is “associated” with the stent, inserted with the stent, positioned with the stent, and expanded by the stent.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 305-7554. The examiner can normally be reached on 8am-4:30pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Sarah K Webb
Examiner
Art Unit 3731

SW
March 3, 2003



Michael Milano
Supervisory Patent Examiner
Art Unit 3700